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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,290	01/31/2002	Raja G. Achari	NPCI-0294/719-127CON3	1773

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EXAMINER
KIM, JENNIFER M

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/062,290	Applicant(s) ACHARI ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 35-61* is/are pending in the application.

4a) Of the above claim(s) *1,2,12 and 18-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-11,13-17,24-30 and 35-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election of Group II (claims 3-11, 13-17, 24-30 and 35-61), drawn to a pharmaceutical composition comprising a dopamine receptor agonist in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1, 2, 12 and 18-23 are withdrawn from consideration since they are non-elected inventions.

Claim Objections

Claim 55 is objected to because of the following informalities: Claim 55 is redundant since it is a duplicate of claim 54. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36 and 47-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,436,950 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter since they claims are drawn to same technical fields, which constituted with same active agents, same reducing agents and same pH value.

Claims 41-44, 50 and 52-57 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 09/665,500. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter since the claims are drawn to same technical fields, which constituted with same active agents, same solubilizing agents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 24-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-32 and 39 of copending Application No. 09/882,746. Although the conflicting claims are not identical, they are not

patentably distinct from each other because it encompasses same subject matter since the claims are drawn to same technical fields, which constituted with same composition comprising same active agents with same onset of action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 3, 39, 47-49, 50, 51 and 59-61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62, 71 and 73 of copending Application No. 10/062,021 and claims 62-71 of copending Application No. 10/062,020. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompasses same subject matter since the claims are drawn to same technical fields, which constituted with same composition comprising same active agents with same mechanism of action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5, 13, 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Cicinelli et al. (1996) in view of American Hospital Formulary Service (1988) and Heaton et al.(1995).

With regard to claim 3, Cicinelli et al. teach a dopamine receptor agonist (bromocriptine) in a nasal spray composition.

American Hospital Formulary Service on page 2133, left-hand side, under Chemistry and Stability, teaches bromocriptine as a dopamine receptor agonist.

Applicants' recitation in claim 3 of an intended use and onset of action set forth in claims 24-29 not found in the prior art does not represent a patentable limitation since such fails to impart any physical limitation to the composition that is not found in the prior art composition.

With regard to claims 3-5 and 13, 24-29, Heaton et al. on the abstract disclose an aqueous nasal spray apomorphine preparation.

Applicants' recitation of onset of action set forth in claims 24-29 not found in the prior art does not represent a patentable limitation since such fails to impart any physical limitation to the composition that is not found in the prior art composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 39, 41-44, 46, 50, 52-58 rejected under 35 U.S.C. 103(a) as being unpatentable over Azria et al. (U.S.Patent No. 4758423) in view of DRUG FACTS AND COMPARISONS (1997).

Azria et al. on the abstract, column 2, lines 51-69, column 3, line 36, column 4, lines 53-55 and column 6, claims 1, 2 and 4, teach a pharmaceutically acceptable nasal spray comprising bromocriptine, polyethylene glycol, and propylene glycol.

DRUG FACTS AND COMPARISONS on page 3507 lines 1-8, teaches that bromocriptine is a dopamine receptor agonist.

The difference between primary reference and Applicants' claimed invention further comprising glycerin and lack of illustrative example of bromocriptine nasal liquid spry comprising the specified glycol derivatives. However, one of ordinary skill in the art would have been motivated to formulate bromocriptine nasal spray comprising the specified glycol derivatives with reasonable expectation of success since Azria et al. teach that any glycol especially propylene glycol and polyethylene glycol are useful in formulating nasal bromocriptine nasal liquid spray.

The surfactants and other additives (glycerin) to be used are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations.

Further, Applicants' recitation in claim 3 of an intended use and outcome of reducing adverse nasal effects not found in the prior art does not represent a patentable limitation since such fails to impart any physical limitation to the composition that is not found in the prior art composition.

Claims 3-11, 13-17, 24-30, and 35-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Illum (WO 99/27905) in view of Merkus (U.S.Patent No. 5,756,483) and further view of El-Rashidy et al. (U.S.Patent No. 5,888,534).

Illum at page 1, lines 3-5, page 6, lines 5-10, teach a composition for nasal administration of apomorphine or salt thereof, for treating erectile dysfunction in a mammal.

Illum at page 3, lines 20-24, page 4, lines 17-20, teach that above composition minimize side effects and adverse reactions unlike other nasal formulation of apomorphine are associated with unacceptable side effects and therefore not suitable, and the sublingual formulation resulted green coloration of the tongue, with poor taste and mucosal ulceration.

Illum at page 9, line 1, and lines 16-25, teach that apomorphine composition can be employed with a variety of pharmaceutically acceptable excipient, comprising carboxymethyl cellulose, with a buffer system in a liquid composition.

Illum at page 16, lines 1-5, teach that liquid nasal composition can also contain any other pharmacologically-acceptable, non-toxic ingredients such as preservatives.

Illum at page 14, line 30 through page 15, line 2, teach the range of pH of nasal by the presence of appropriate buffers within applicants' range as set forth in claim 36.

El-Rashidy et al. teach on column 7, TABLE 1 that the polyethylene glycol and glycerin are suitable components of apomorphine formulation.

El-Rashidy et al. at column3 through column 4, Tables I-III, teach sublingual apomorphine formulation containing sugar alcohol (mannitol), stabilizing agent (ascorbic acid, glycerin, polyethylene glycol).

Merkus teaches on the abstract, column 3, line 10 through column 4, lines 10, and column 6, lines 45-50, column 8, Example 2-3, teach various formulation of apomorphine containing sodium metabisulfite, water, propylene glycol, methylcellulose, surgar alcohol (sorbitol) and derivatives.

Merkus on the abstract, column 4, lines 16-19, lines 37-40, column 5, lines 7-13 and column 6, lines 40-50 teaches intranasal formulation of apomorphine can be formulated with many other excipients, known from the pharmaceutical literature, can be added, such as preservatives, surfactant, co-solvents, adhesives, antioxidants, buffers, viscosity enhancing agents and agents to adjust the pH or the osmolarity.

The difference between Illum reference and Applicants' invention is that combined formulation of apomorphine and the specific humectants, specific buffer agents, and stabilizing agents (prolylene glycol, glycerin, sugar alcohol etc.).

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Illum such that apomorphine composition to formulate with a variety of pharmaceutically acceptable excipients as they are generically combined with apomorphine formulations by above references. One of ordinary skill in the art would have been motivated to make such a modification since Illum teach that any pharmaceutically acceptable excipient and non-toxic ingredients, and any appropriate buffers can be formulated with apomorphine.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

It is suggested that Applicants submit a declaration to clearly establish a surprising and unexpected result using Applicants' teaching.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Jennifer Kim
Patent Examiner
Art Unit 1617

jmk
December 2, 2002